



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,827	07/31/2001	Richard K. Haynes	LEA 33 820	8606

35969 7590 08/07/2003

JEFFREY M. GREENMAN  
BAYER PHARMACEUTICALS CORPORATION  
400 MORGAN LANE  
WEST HAVEN, CT 06516

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 08/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/743,827

Applicant(s)

HAYNES ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 16-23 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 17, 18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 and 23 is/are rejected.
- 7) ☒ Claim(s) 16, 19, 20, 22 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

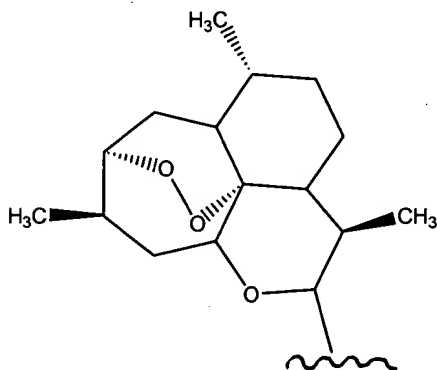
- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-13, 16-23, and 28 are pending in this application.

#### *Election/Restrictions*

Applicant's election with traverse of the specific embodiment, example 7, in Paper No. 11, filed 6-24-03 is acknowledged. In a telephone conversation with the Examiner on July 14, 2003, Mr. William Gray indicated that he elects claims 16-23 and 28 for prosecution. The traversal is on the ground(s) that "the claimed materials have a common property or activity, and a common structural element, therefore it is deemed that the requirements for unity of invention are met. In addition, the claimed compounds belong to a recognized class of chemical compounds thereby satisfying the unity of invention requirement in a second way." This is not found persuasive because the following significant structural element:



does not provide a contribution over the art. (See the rejections under 35 U.S.C 102 below.) Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Art Unit: 1626

Moreover, to not restrict herein, would impose a burden on the examination of this application.

The following generic concept as depicted in claim 16 is identified for examination along with the elected embodiment: Y represents a C-linked heteroaryl or heterocyclalkyl group. The remaining subject matter of claims 16, 19, 20, 22, 23, and 28 in part and claims 1-13, 17,18, and 21 in their entirety is withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 16, 19, 20, 22, 23, and 28 in part and claims 1-13, 17,18 and 21 in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

The subject matter of claim 17 is not within the scope of the generic concept identified by the examiner. However, the subject matter of claim 28, which depends from claim 17, is within the scope of the generic concept identified by the examiner. Therefore, it is suggested that Applicant combine the subject matter of claims 17 and 28.

Claims 16, 19, 20, 22, 23, and 28 in part are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

Art Unit: 1626

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Heterocycles 45(6): 1055-1058 (1997), Jung et al.; WO 99/33461 Posner et al.; US Patent 5,225,562 McChesney et al.; STN International @ CAPLUS Database, Accession No. 1997:526864, Mai et al. Tap Chi Hoa Hoc (1997), 35(1), 11-13, abstract.

Jung et al. teach analogs of artemisinin which are useful as antimalarial drugs. Jung et al. teach an example of the instant compound on page 1056, compound 12.

Posner et al. teach C-10 carbon-substituted artemisinin-like trioxane compounds having antimalarial activities. Posner et al. teach an example of the instant compound on page 17, compounds 17a, 18, and 19.

McChesney et al. teach a method of preparing (+)-deoxoartemisinin compounds which are useful as an antimalarial agent. McChesney et al. teach an example of the instant compound in column 10, claim 23.

Mai et al. teach the synthesis of new artemisinin derivatives containing a C-C bond at position 12. Mai et al. teach an example of the instant compounds in RN 194409-61-5.

***Claim Objections***

Claims 19, 20, and 22 are objected to because they depend from claim 16 which was rejected. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

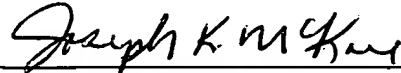
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Art Unit: 1626

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



---

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

August 1, 2003